AUG 2 4 2000

K002021

510(k) Summary of Safety and Effectiveness

Trade Name:	Hemostatix #12 Scalpel Blade
Common Name:	Thermal Scalpel
Classification Name:	Electrosurgical cutting and coagulation device and accessories (§ 878.4400)

Official Contact: Alicia E. Farage
Senior Regulatory Affairs Specialist
Smith & Nephew, Inc.
ENT Division
2925 Appling Road
Bartlett, TN 38133

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Date Prepared: August 4, 2000.

Intended Use

Indications for use of the #12 Scalpel Blade are for Head & Neck, General, Plastic, and Oral surgical procedures.

The #12 Scalpel Blade, when used with the Model 600D controller as a heated blade is designed to retain the precise, clean cutting characteristics of a traditional steel scalpel and to minimize blood loss by simultaneously sealing blood vessels as they are cut. The thermally heated blade provides hemostasis with minimum tissue damage and virtually no muscle stimulation.

Materials

The #12 blades will be made of stainless steel, the same material as the currently cleared #10 and #15 scalpel blades in the Hemostatix Thermal Surgery System. The #12 blades will also use the same inks, non-stick coatings, and be manufactured on the same equipment that is used to manufacture the current #10 and #15 scalpel blades. The only difference is an edge coating that is no longer available and will have to be replaced with a comparable product from the same manufacturer. The product initially used was Dupont's Vydax 1000/IPA. The product selected to replace Vydax is Dupont's Krytox 1000/IPA.

Design Features

The #12 Scalpel Blade contains the same design elements as the #10 and #15 Hemostatix Scalpel Blades manufactured by Smith & Nephew, Inc., ENT Division. The only difference between the blades is the configuration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 4 2000

Ms. Alicia E. Farage
Senior Regulatory Affairs Specialist
Smith & Nephew, Inc.
ENT Division
2925 Appling Road
Bartlett, Tennessee 38133

Re: K002021
Trade Name: Hemostatix #12 Scalpel Blade
Regulatory Class: II
Product Code: GEI
Dated: June 30, 2000
Received: July 3, 2000

Dear Ms. Farage:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K002021
Device Name: Hemostatix #12 Scalpel Blade

Indications For Use:

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Revised 8-4-2000

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002021

Prescription Use ✓ OR Over-The- Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)